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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/348,954	07/07/1999	JOHN A GENT	C-309	6008

7590

04/04/2003

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EXAMINER

WEBB, JAMISUE A

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 04/04/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No.		Applicant(s)	
	09/348,954		GENT ET AL.	
	Examiner		Art Unit	
	Jamisue A. Webb		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,10-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,10-17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 1/23/03 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09348,954 is acceptable and a CPA has been established. An action on the CPA follows.

Response to Amendment

2. The amendment filed 1/23/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant has added the phrase "formed of a flexible plastic sheet material" considered new matter, the specification states that the pouch can be made of plastic material and never discusses the flexibility of the plastic material and also never discussed it being made from a sheet material. Plastic has the ability to be rigid and not all plastics are formed into sheets therefore the terms "flexible" and "sheet" are considered new matter. Applicant has also added the phrase "predeterminedly sized", which is considered new matter. All that the specification states is the use of an ostomy pouch, and whereas it is well known that ostomy pouches have openings which encircle the stoma, the opening does not always have to be predeterminedly sized, it can be adjustable to fit the person wearing the pouch at the time of application. The applicant has also added that the carrier is attached to the interior surface portion of the envelope "distal" to the base of the envelope, which the limitation of "distal to the base" is considered new matter. All that is outlined in the specification is the carrier can be

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attached to the inside of the pouch, the specification gives nothing as to where the base is located and that the carrier is attached distal to it.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-8, 10-17 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations of "flexible" plastic "sheet" material, "predeterminedly sized" and "distal" are considered new matter, not supported by the original specification. See detailed reasoning above.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-4, 17 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Lesko (5,643,234).

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7. With respect to Claim 1 and 19: Lesko discloses the use of an ostomy pouch (10) with an envelope (12,14), where the envelope is made of flexible thermoplastic sheet material (column 3, lines 6-10). Lesko discloses the pouch having an opening (28) that fits over the stoma of the wearer. Lesko also discloses the use of carrier (60) that contains a malodour counteractant (40).

8. With respect to Claim 2: Lesko discloses the malodour counteractant being a foam layer partially coating the carrier 60 (See Figure 6).

9. With respect to Claim 3: Column 3, line 66 to column 4, lines 8.

10. With respect to Claim 4: Lesko discloses the carrier comprises an absorbent matrix (55)

11. With respect to Claim 17: See Column 3, lines 52-61.

12. Claims 1, 2, 4-6, 16, 17 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Gent (5,860,959).

13. With respect to Claims 1, 4, 5, 16, 17 and 19: Gent discloses the use of an ostomy pouch that consists of an envelope and an aperture (column 3, lines 22-29). Where a hygroscopic matrix is attached to the wall of the interior of the envelope (column 4, lines 13-20) and where the matrix can include malodour counteractant such as a fragrance (column 4, lines 21-23).

14. With respect to Claim 3: column 4, lines 18-20

15. With respect to Claim 6: See abstract and Claim 1.

Claim Rejections - 35 USC § 103

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 11, 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gent in view of Mayhan et al. (4,863,445).

18. With respect to Claims 11 and 12: Gent, according to claim 1, discloses the addition of anti-microbial compositions in the hygroscopic matrix, however is silent as to what composition that is. Mayhem discloses the use of an anti-microbial agent added to collection devices such as ostomy bags (column 3, lines 47-57) and where the anti-microbial is an oxidizing agent such as hydrogen peroxide generator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the anti-microbial composition of Gent, be the hydrogen peroxide generator of Mayhan, in order to provide a composition which would have an inhibiting or killing effect on microbes in the collected body fluid, to prevent infection of patients. (See Mayhan, column 1)

19. With respect to Claims 14 and 15: Mayhan discloses the hydrogen peroxide generator can be sodium perborate (column 4, lines 24-33).

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jessup et al. (4,203,445) discloses the use of an odor absorbent cake within an ostomy

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pouch, and Palumbo et al. (6,508,794) and Schneider et al. (5,417,677) disclose the use of an ostomy pouch with an absorbent member.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jamisue A. Webb whose telephone number is (703) 308-8579.

The examiner can normally be reached on M-F (7:30 - 4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703)308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jaw
March 28, 2003


WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700